REMARKS

Applicant respectfully requests further examination and reconsideration in view of the arguments set forth fully below. In the Office Action mailed December 6, 2005, claims 1-20 have been rejected. In response, the Applicant has submitted the following remarks. Accordingly, claims 1-20 are pending. Favorable reconsideration is respectfully requested in view of the remarks below.

Information Disclosure Statement

Within the Office Action, it is stated that the Information Disclosure Statement filed on May 24, 2004 fails to comply with 37 C.F.R. §1.98 (a) (2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion with causes to be listed, and all other information or that portion with causes to be listed. It is further stated that the references crossed out on the initial 1449 Forms have been placed in the application, but have not be considered.

In response, the Applicant has included herein a number of those references crossed out on the original 1449 Form on a new 1449 Form, with copies of those references. The Applicant will submit the remainder of those crossed out references under separate cover.

Rejections Under 35 U.S.C. §112

Within the Office Action, claims 1-20 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. It is further stated that the Specification does not adequately define how a sudden cardiac death risks score is calculated. In response, the Applicant respectfully directs the Examiner to the number of passages in the present Specification that adequately define how a sudden cardiac death risk score is calculated. Page 7, paragraphs 29-31 describe how each of the devices described in the preceding paragraphs of the Specification can include a software program that use one or more of the measurements described to calculate an SCD score. Page 9,

paragraph 40 includes a description of a SCD prediction system 110 with can interface and communicate with the ECG test system 26. On pages 10-11, paragraphs 43-45 it is described how the SCD prediction system 110 acquires all the data available for the particular patient from the systems in order to evaluate the test results, and analyze differences or changes in the patient's heart condition. On page 13, paragraphs 51-53, the Specification provides a description of a diagnosis module 158 which provides medical diagnosis and an SCD risk score based on ECG measurements, the images measurements, the medical measurements, and/or correlations. Finally, on pages 14-15, paragraph 56, it is described how the diagnosis module 158 can calculate a SCD risk score. In light of the above paragraphs, the Applicant respectfully submits that the Specification indeed adequately defines how a sudden cardiac death risk score is calculated.

Rejections Under 35 U.S.C. §102

Within the Office Action, claims 1-2, 10-11 and 18 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,042,497 to Shapland et al (hereinafter Shapland). The Applicant respectfully disagrees with this rejection. Specifically, it is stated within the Office Action that Shapland discloses a method predicting sudden cardiac death in a patient comprising acquiring patient data from a plurality of medical equipment databases and further providing a prediction when a patient is at an elevated risk of a sudden death cardiac arrhythmia.

Shapland teaches a system for predicting and preventing cardiac arrhythmias reusing combination with an implanted arrhythmia treatment device comprising means for sensing the neural activity of a patient and triggering implanted arrhythmia treatment device to take preventative and curative actions for an impending arrhythmia upon an elevation of the neural activity (Shapland, abstract). However Shapland does not teach calculating a sudden cardiac death risk score.

In contract to the teachings of Shapland, the method of the present invention includes acquiring patient data and analyzing the patient data to determine a sudden cardiac death risk score.

Claim 1 is directed to a method of predicting sudden cardiac death in a patient, the method comprising acquiring patient data from a plurality of medical equipment databases, and analyzing the patient data to determine a sudden cardiac death risk score. As described above, Shapland does not teach analyzing the patient data to determine a sudden cardiac death risk score. For at lease these reasons, the independent claim 1 is allowable over the teachings of Shapland.

Claims 2 and 10 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Shapland. Accordingly, claims 2 and 10 are also allowable as being dependent upon an allowable base claim.

Claim 11 is directed to a method of predicting sudden cardiac death of a patient, the method comprising analyzing multiple independent indications of sudden cardiac death acquired from a plurality of medical equipment databases and generating a sudden cardiac death risk score. As described above, Shapland does not teach generating a sudden cardiac death risk score. For at least these reason, the independent claim 11 is allowable over the teachings of Shapland.

Claim 18 is directed to a sudden cardiac death prediction system comprising an acquisition module connected to a plurality of inputs for receiving patient data and image data from plurality of databases and means for analyzing the patient data and image data to generate a sudden cardiac death prediction score based on the patient data and the image data. As described above, Shapland does not teach means for analyzing the patient data and the image data to generate a sudden cardiac death prediction score based on the patient data and the image data. For at least these reasons, the independent claim 18 is allowable over the teachings of Shapland.

Rejections Under 35 U.S.C. §103

Within the Office Action, claims 1-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,370,423 to Guerrero et al. (hereinafter Guerrero). The Applicant respectfully disagrees with this rejection.

Guerrero teaches a method of analyzing biological signals representative of voltages changes, including obtaining an analog biological signal representative of voltage changes, using digital processing software to digitize the biological signal, displaying the process biological signal in analog form on the display in a time compressed format, wherein an amount of compression for the time compressed format is selected such that graphical patterns are made perceivable on the display that signify an abnormality in the biological signal, and visually analyzing the biological signal under the display to characterize the abnormality (Guerrero, abstract). However, Guerrero does not teach analyzing the patient data to determine a sudden cardiac death risk score.

Once again, the independent claim 1 is directed to predicting sudden cardiac death of a patient comprising acquiring patient data from a plurality of medical equipment databases and analyzing the patient data to determine a sudden cardiac death risk score. As described above, Guerrero does not teach analyzing the patient data to determine a sudden cardiac death risk score. Furthermore, there is no hint, teaching, nor suggestion in Guerrero to lead a person having ordinary skill in the art to conclude that determining a sudden cardiac death risk score would be obvious in light of Guerrero. For at least these reasons, the independent claim 1 is allowable over the teachings of Guerrero.

Claims 2-9 depend upon the independent claim 1. As discussed above, the independent claim is allowable over the teachings of Guerrero. For at least these reasons, claims 2-9 are allowable as being dependent upon an allowable base claim.

Within the Office Action, claims 1, 12, and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,261,230 to Bardy et al. (hereinafter Bardy). The Applicant respectfully disagrees with this rejection.

The Applicant respectfully points out that Bardy does not teach analyzing patient data to determine a sudden cardiac death risk score.

Claims 1, 12 and 20 are all directed to a method, a computer program, and a medical device for determining a risk or predicting sudden cardiac death, and all of these claims including calculating a sudden cardiac death risk score based on patient data. As discussed above, Bardy does not teach calculating a sudden cardiac death risk score. For at least these reasons, claims 1, 12 and 20 are allowable over Bardy.

Within the Office Action, claims 13 and 17 have been rejected under 35 U.S.C. §103(a) as being patentable over Bardy in view of U.S. Patent No. 5,276,612 to Selker. Claim 13 is dependent upon the independent claim 12. As discussed above, the independent claim 12 is allowable over the teaching of Bardy. For at least these reason, claim 13 is allowable as being dependent upon an allowable base claim.

The independent claim 17 is directed towards a method of displaying a prediction of sudden cardiac death, including a single report including a sudden cardiac death risk score. The Applicant submits that Selker also does include calculating a cardiac death risk score, and therefore claim 17 is also allowable over the teachings of Bardy and Selker.

Within the Office Action, claims 14, 15 and 19 have been rejected under rejected under 35 U.S.C. §103(a) as being unpatentable over Bardy in view of U.S. Patent No. 5,509,425 to Feng (hereinafter Feng). The Applicant respectfully submits that Feng also does not teach calculating a cardiac death risk score.

Claims 14 and 15 are dependent upon the independent claim 12. As discussed above independent claim 12 is allowable. For at least these reasons, claims 14 and 15 are allowable as dependent upon an allowable base claim.

Independent claim 19 is directed towards computer program embodied by a computer readiable medium capable of being executed by a computer program for use in a medical device, the computer program comprising instructions to acquire patient data and image data from the medical device, instructions to analyzing the patient data and

image data and instructions to calculate a sudden cardiac death risk score based on the patient data and the image data. As discussed above, neither Bardy, Feng nor their combination teach instructions to calculate a sudden cardiac death risk score based on the patient data and the image data. For at least these reasons, the independent claim 19 is allowable over the teachings Bardy and Feng.

Within the Office Action, claim 16 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Bardy in view of U.S. Patent No. 5,819,007 to Elghazzawi (hereinafter Eghazzawi). Claim 16 is dependent upon the independent claim 12. As described above, the independent claim 12 is allowable. For at least these reasons, claim 16 is allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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